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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/532,263	03/22/2000	Douglas James Hilton	10296A	8294

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09/05/2003

Scully Scott Murphy & Presser
400 Garden City Plaza
Garden City, NY 11530

EXAMINER

MERTZ, PREMA MARIA

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 09/05/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/532,263	HILTON, DOUGLAS JAMES	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,8,9,11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5 and 12 is/are rejected.
- 7) ☒ Claim(s) 8-9, 11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>19</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/7/03 in Paper No. 19 has been entered.

Specification

2. A new title of the invention is required because the word "novel" is not considered as part of the title of an invention and the Patent and Trademark Office does not include such words at the beginning of the title of the invention. It is suggested that the word "novel" be deleted from the title of the invention to read "nucleic acid encoding α chain of human IL-11 receptor". See MPEP § 606.01.

3. On page 21, Table 2 of the instant specification are recited unbranched nucleotide sequences with 10 or more bases. According to 37 CFR 1.821 © reference must be made to these sequences by use of the sequence identifier preceded by SEQ ID NO. in the text of the description or claims. Appropriate correction is required.

In the event that these sequences do not have SEQ ID NO:s, then Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences recited in the claims of the instant application and encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37

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C.F.R. §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification and/or claims will also need to be amended so that they comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

Claim Rejections - 35 USC § 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description in this case only sets forth SEQ ID NO:4 and 5 and equivalent degenerative codon sequences thereof and therefore the written description is not commensurate in scope with the claims drawn to a nucleic acid molecule which encodes a “mammalian IL-11 receptor α -chain”.

The specification discloses a nucleic acid molecule encoding an α -chain of human IL-11 receptor having the amino acid sequence shown in SEQ ID NO:5. This amino acid sequences meets the written description and enablement provisions of 35 U.S.C. 112, first paragraph.

However, the indicated claim is directed to encompass mammalian homologues of the disclosed amino acid sequences having undisclosed amino acid sequences which correspond to sequences

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from other species. None of these amino acid sequences meet the written description provision of 35 USC 112, first paragraph.

In the specification on page 3, lines 13-16, Applicants disclose that mammalian includes humans, sheep, cows, pigs, goats, horses, mice, rats, pigs, cats, dogs etc. *Vas-Cath Inc. v. Makurhar*, 19 USPQ2d 1111, makes clear that applicant must convey with reasonable clarity to those skilled in the art, as the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry whatever is now claimed (see page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. (See *Vas-Cath Inc. v. Makurhar*, page 1116).

With the exception of human amino acid sequences as set forth in SEQ ID NO: 5, the skilled artisan can not envision the detailed chemical structure of the encompassed amino acid sequences and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that is part of the invention and reference to a potential method for isolating it, the amino acid sequence itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ 2d 1481, 1483. Weighing all factors in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the Applicant was in possession of the claimed invention.

4b. Claim 12 is also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule which encodes an α -chain of human

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IL-11 receptor polypeptide as set forth in SEQ ID NO:5, does not reasonably provide enablement for a nucleic acid molecule encoding mammalian IL-11 receptor α -chain said nucleic acid further defined by the ability of an oligonucleotide selected from SEQ ID NO:6-10 to hybridize under the conditions recited in claim 12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 12 is overly broad in the recitation of "mammalian" IL-11 receptor α -chain. No guidance is provided in the specification as to how one of ordinary skill in the art would generate isolated polynucleotides encoding polypeptides from all mammals, that would exhibit the same biological function as the human IL-11 receptor α -chain polypeptide exemplified in the specification. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Given the breadth of claim 12 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification

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and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention.

4c. Claims 1, 5, 12 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description in this case only sets forth SEQ ID NO:5 and equivalent degenerative codon sequences thereof and therefore the written description is not commensurate in scope with the claims drawn to a nucleic acid molecule which encodes variants of the IL-11 receptor α -chain. The specification discloses a nucleic acid molecule encoding an α -chain of human IL-11 receptor having the amino acid sequence shown in SEQ ID NO:5. This amino acid sequences meets the written description and enablement provisions of 35 U.S.C. 112, first paragraph. However, the indicated claims are directed to encompass variants of the nucleic acid encoding human IL-11 receptor α -chain. None of these claimed nucleic acid molecules encoding variant amino acid sequences meet the written description provision of 35 USC 112, first paragraph.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Reiger et al (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlay, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of naturally occurring

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allelic sequences encompassed by the claims are not defined. With the exception of SEQ ID NO:4, the skilled artisan cannot envision the detailed structure of the encompassed nucleic acid molecules and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Furthermore, In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Support for variants is provided in the specification on pages 7-8. However, no disclosure, beyond the mere mention of variants is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

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Therefore only an isolated nucleic acid molecule comprising a nucleic acid sequence as set forth in SEQ ID NO:4 encoding a polypeptide of amino acid sequence set forth in SEQ ID NO:5 and equivalent degenerative codon sequences thereof, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

4d. Claims 1, 5, are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description in this case only sets forth SEQ ID NO:5 and equivalent degenerative codon sequences thereof and therefore the written description is not commensurate in scope with claims drawn to a nucleic acid molecule which encodes human IL-11 receptor α -chain and can hybridize to SEQ ID NO:4.

Claim 1 recites “hybridizes to SEQ ID NO:4” and encompasses a genus of nucleic acid molecules which could comprise only portions of the full-length sequence of SEQ ID NO:4 as well as variants having one or more nucleotide deletions, insertions and/or additions made to SEQ ID NO: 4. The specification and claims do not indicate what are the distinguishing attributes shared by the members of the genus for which the common portion is responsible for functional activity. The specification and claim do not place any limit on the number of nucleotides that may be added to the portions since the claim is not limited to the full-length SEQ ID NO:4. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide a written description as to what

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changes should be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure. No common structural and functional attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, nucleic acid molecules that encode human IL-11 receptor α -chain and hybridize to SEQ ID NO:4 are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus.

4e. Claims 1, 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid molecule comprising the nucleotide sequence set forth in SEQ ID NO:4, does not reasonably provide enablement for a nucleic acid molecule encoding an α -chain of human IL-11 receptor that hybridizes to SEQ ID NO:4 as recited in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claimed genus of polynucleotide molecules encompasses variants, however, the specification does not teach how to make a polynucleotide molecule encoding a polypeptide having an amino acid sequence less than SEQ ID NO:5. The specification only enables a nucleic acid molecule encoding a protein of amino acid sequences set forth in SEQ ID NO:5, and is not enabled for a nucleic acid molecule of nucleotide sequence anything less than what is disclosed in SEQ ID NO:4.

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The issue in the instant case is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. Applicants have not taught how to make the instant nucleic acid molecules encoding human IL-11 receptor α -chain comprising nucleotides that hybridize as recited in claim 1. The instant claims are not limited to naturally-occurring compounds and the instant specification does not provide a description of a repeatable process of producing a nucleic acid molecule as claimed.

Due to the large quantity of experimentation necessary to generate the infinite number of derivatives and allelic modifications recited in the claims, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural or functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope. Given the breadth of claims 1, 5 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to practice the claimed invention.

Claim rejections-35 USC § 112, second paragraph

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5. Claims 1, 5 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it recites that the claimed nucleic acid molecule encoding an α chain of human IL-11 receptor hybridizes to both SEQ ID NO:4 and the complement of SEQ ID NO:4 but this is inconceivable.

Conclusion

No claim is allowed.

Claims 8-9, 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Premā Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

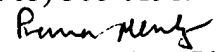
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Premā Mertz Ph.D.
Primary Examiner
Art Unit 1646
August 25, 2003